



OCT 22 2004

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Irwin Naturals
5310 Beethoven Street
Los Angeles, CA 90066

To Whom It May Concern:

The Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.irwinnaturals.com> and has concluded that claims on this web site cause your product "Maximum Strength Phase 2 Carb-Blocker" to be misbranded under the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and FDA's regulations through links on FDA's Internet home page: <http://www.fda.gov>.

Under section 403(r)(6) of the Act, dietary supplement labeling may include claims about the supplement's effect on the structure or function of the human body (structure/function claims), provided that certain requirements are met. [21 U.S.C. § 343(r)(6)(A).] One of these requirements is that the manufacturer of a dietary supplement bearing a "structure/function" claim must have substantiation that the claim is truthful and not misleading. [21 U.S.C. § 343(r)(6)(B).]

The labeling of Maximum Strength Phase 2 Carb-Blocker bears structure/function claims, including the following:

- "[B]lock more carbs and lose more weight.... Eat your favorite pasta, bread...without all the carbs turning to fat."

Under the ingredients list for Maximum Strength Phase 2 Carb-Blocker:

- "Phase 2 white Kidney Bran Extract is the only material clinically proven to block starchy carbohydrates...from turning into fat. ... Of course, this means that those sugar calories won't get stored as fat."
- "Magnolia bark extract...Reduces stress induced cravings..."
- "Chromium Picolinate...-Normalizes...cravings"

We have reviewed these claims and have concluded that they are not supported by competent and reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded within the meaning of sections

403(a)(1) and 403(r)(6)(B) of the Act. [21 U.S.C. § 343(a)(1), (r)(6)(B).] It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded. [21 U.S.C. § 331(a).] It is a violation of section 301(k) of the Act to commit any act with respect to a food if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being misbranded. [21 U.S.C. § 331(k).]

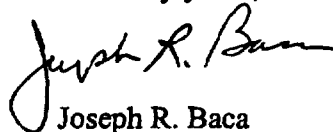
This letter is not an all-inclusive review of your web site and the products that your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct any violations, including the violations identified in this letter. Failure to do so may result in enforcement action, including seizure or injunction, without further notice.

If you have scientific evidence which you believe substantiates that your claims for Maximum Strength Phase 2-Carb Blocker are truthful and not misleading, please provide it to us within fifteen (15) working days of receipt of this letter. Alternatively, please advise this office, in writing and within fifteen working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to ensure that similar violations do not occur in the future. If corrective action cannot be completed with fifteen working days, state the reason for the delay and the time within which the corrections will be made.

Your reply should be sent to the attention of Compliance Officer Quyen Tien at the above address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joseph R. Baca", written in a cursive style.

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition